

CLAIMS

1. A process for purification of optically impure Ramipril to obtain Ramipril(I) having optical purity of at least 99.9 %, which comprises crystallizing optically
5 impure Ramipril from an organic solvent selected from nitromethane, dimethoxymethane, diethoxymethane, and 2,2, -dimethoxy propane and mixtures thereof .
2. The process as claimed in claim 1 wherein the organic solvent is
10 diethoxymethane.
3. A monohydrate of Ramipril(I), characterized by the following X-ray powder diffraction pattern

Diffraction angle <u>2 θ</u>	Relative Intensity (%)
8.7	16
9.2	3
9.4	3
9.7	3
11.2	81
11.6	33
12.2	66
14.54	96
15.7	70
18.0	51
19.7	81
24.5	49
24.8	30

4. The Ramipril(I) monohydrate as claimed in claim 3 having an X-ray diffractogram, or substantially the same X-ray diffractogram, as set out in Figure 1a.
- 5 5. The Ramipril(I) monohydrate as claimed in claim 3 having DSC thermogram as described in Fig. 1c.
6. The Ramipril(I) monohydrate as claimed in claim 3 having TGA thermogram as described in Fig. 1d.
- 10 7. A process for preparation of Ramipril(I) monohydrate comprising of crystallizing optically impure Ramipril from a mixture of water and water-immiscible solvents.
- 15 8. The process claimed in claim 7 wherein the ratio of water-immiscible solvent to water is in the range from 2 to 98% w/w.
9. The process as claimed in claim 8 wherein the said water-immiscible solvent is selected from an aliphatic ester, an acetal, a hydrocarbon or a mixture thereof.
- 20 10. The process as claimed in claim 8 wherein the said water-immiscible solvent is selected from diisopropyl ether, diethoxymethane, 2,2-dimethoxy propane, cyclohexane, methyl isobutyl ketone and ethyl acetate or a mixture thereof.
- 25 11. A process for preparation of Ramipril(I) monohydrate comprising of crystallizing optically pure Ramipril(I) from water.
12. A pharmaceutical composition comprising an effective ACE inhibitory amount of Ramipril(I) monohydrate as claimed in any preceding claims, together with
30 one or more pharmaceutically acceptable carriers, diluents or excipients thereof.